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UNITED STATES DISTRICT COURT  
DISTRICT OF UTAH

NUTRACEUTICAL CORPORATION and  
SOLARAY, INC.,

Plaintiffs,

v.

LESTER CRAWFORD, D.V.M., Acting  
Commissioner, U.S. Food and Drug  
Administration, et al.,

Defendants.

Case No. 2:04CV00409 TC

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DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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The above-named Defendants move for summary judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure, dismissing all of Plaintiffs' claims with prejudice. Defendants seek summary judgment on Plaintiffs' Cause of Action I on the ground that the Food and Drug

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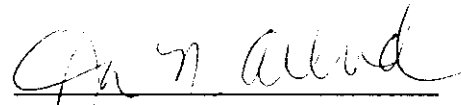
Administration (“FDA”), in promulgating the Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 Fed. Reg. 6788 (Feb. 11, 2004) (“Final Rule”), satisfied its burden of proving that all ephedrine alkaloid-containing dietary supplements (“EDS”) are adulterated because they present an unreasonable risk of illness or injury. Defendants seek summary judgment on Plaintiffs’ Causes of Action II and III on the ground that Congress, in the Federal Food, Drug, and Cosmetic Act, has mandated certain differences in the way dietary supplements and foods are regulated. Defendants seek summary judgment on Plaintiffs’ Cause of Action IV on the grounds that FDA followed the required rulemaking procedures when promulgating the Final Rule, and that the risk-benefit analysis used to determine unreasonable risk in the Final Rule did not require a separate notice-and-comment rulemaking because it is not a substantive rule. Defendants seek summary judgment on Plaintiffs’ Cause of Action V on the ground that the Final Rule does not constitute an unconstitutional taking, so Plaintiffs are not entitled to any compensation from the government.

This motion is accompanied by a memorandum of law setting forth in detail the basis for Defendants’ motion.

DATED this 4th day of November, 2004.

Respectfully submitted,

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United States Attorney



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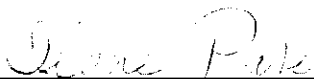
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CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of November, 2004, I caused to be served by regular mail, postage prepaid, copies of "DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT" addressed as follows:

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